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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO	
09/871,282	05/31/2001	Philip Shi-Lung Yu	YOR920010300US1	YOR920010300US1 8621	
35526	7590 09/13/2005		EXAMINER		
DUKE. W. Y			TOMASZEWSI	KI, MICHAEL	
YEE & ASSO P.O. BOX 802	CIATES, P.C.		ART UNIT	PAPER NUMBER	
	DALLAS, TX 75380			3626	
			DATE MAILED: 09/13/2003	5	

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
	09/871,282	YU ET AL.				
Office Action Summary	Examiner	Art Unit				
	Mike Tomaszewski	3626				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1) Responsive to communication(s) filed on <u>31 May 2001</u> .						
2a) This action is FINAL . 2b) ⊠ This	action is non-final.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
4) ☐ Claim(s) 1-21 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 1-21 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or election requirement.						
Application Papers						
9) The specification is objected to by the Examiner.						
10)⊠ The drawing(s) filed on <u>31 May 2001</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 						
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:					

DETAILED ACTION

Notice To Applicant

This communication is in response to the application filed on 31 May 2001.
 Claims 1-21 are pending.

Claim Rejections - 35 USC § 112

- 2. The following is a quotation of the second paragraph of 35 U.S.C. 112:
 - The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 3. Claims 11-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- (A) Claims 11-13 recite three different instructions for the "fourth instructions." It is unclear whether each instruction is to be considered as an individual instruction (i.e., fourth instruction, fifth instruction, and sixth instruction) or whether each instruction

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should be considered as a set (i.e., all are to be considered as part of the fourth instructions).

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 5. Claims 1, 3, 8, 10, 15 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Bouthiette (5,788,079; hereinafter Bouthiette).
- (A) As per Claim 1, Bouthiette discloses a method of packaging medications on demand, the method comprising:
 - (a) grouping medications into dosage groups, wherein the dosage groups contain at least one element of medication and each element of medication in a dosage group should be taken by a patient at substantially

the same time as other elements of medication in the same dosage group (Bouthiette: col. 1, lines 12-19; Fig. 7 and 8);

- (b) placing each dosage group of medication into a separate compartment in a package (Bouthiette: col. 1, lines 12-19; Fig. 7 and 8);
- (c) covering the compartments of the package and labeling compartments with patient customized information indicating a time for which the associated medications within the compartment should be taken by a patient, wherein covering the compartments provides a cover such that removal of a dosage group provides an indication to a patient that the dosage group has been taken by the patient (Bouthiette: col. 6, lines 5-10; Fig. 7 and 8).
- (B) As per Claim 3, Bouthiette discloses the method as recited in Claim1, wherein labeling compartments further comprises providing instructions about use of at least one of the medications (Bouthiette: col. 6, lines 5-10).
- (C) Claim 8 differs from method Claim 1 by reciting "A computer program product in a computer readable media..." As per these elements, Bouthiette's system includes a computer, computer program and a printer (Bouthiette: col. 6, lines 16-17). As such, it is readily apparent that Bouthiette's system is controlled by a computer program stored in a computer readable media. The remainder of system Claim 8 repeats the same

limitations of method Claim 1, and is therefore rejected for the same reasons given above for Claim 1, and incorporated herein.

- (D) Claim 10 substantially repeats the same limitations of Claim 3, and is therefore rejected for the same reasons given for those claims.
- (E) Claim 15 differs from method Claim 1 by reciting hardware elements, namely a medication grouper, a placement unit, a package sealer and a labeler. As per these elements, Bouthiette teaches:
 - (a) a medication grouper which groups medications into dosage groups (Bouthiette: col. 3, line 4);
 - (b) a placement unit which places each dosage group of medication into a separate compartment in a package (Bouthiette: col. 4, line 3);
 - (c) a package sealer which covers the compartements of the package (Bouthiette: col. 4, lines 10-16); and
 - (d) a labeler which labels compartments with patient information indicating a time for which the associated medications within the compartment should be taken by a patient (Bouthiette: col. 6, lines 11-17).

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The remainder of system Claim 15 repeats the same limitations of method Claim 1, and is therefore rejected for the same reasons given above for Claim 1, and incorporated herein.

(F) Claim 17 substantially repeats the same limitations of Claim 3, and is therefore rejected for the same reason given for that claim.

Claim Rejections - 35 USC § 103

- 6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 7. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bouthiette as applied to claim 1 above, and further in view of Machblitz (4,429,792; hereinafter Machblitz).
- (A) As per Claim 2, Bouthiette fails to expressly disclose the method as recited in Claim1, wherein the packaging comprises one of a blister pack and a foil pack.

Nevertheless, this feature is old and well known in the art, as evidenced by Machblitz. In particular, Machblitz discloses the method as recited in Claim1, wherein the packaging comprises one of a blister pack and a foil pack (Machblitz: col. 2, lines 54-56; col. 4, lines 28-29).

One of ordinary skill would have found it obvious at the time of the invention to include the aforementioned feature of Machblitz within the Bouthiette system with the motivation of protecting the medication against moisture and oxidation (Machblitz: col. 2, lines 49-50).

Examiner also notes the following: (1) Although the Bouthiette system does not explicitly describe its packs as "blister packs" or "foil packs," the packs appear to be so (Bouthiette: Fig. 8) and (2) Applicant's admission, in the background of the invention of the present application (09/871282), that "Blister packs and foil packs are types of packaging medications that *are well known in the art and commonly used* [italics added] for 'over the counter' drugs."

- (B) Claims 9 and 16 substantially repeat the same limitations as Claims 2 above, and are therefore rejected for the same reasons given for that claim.
- 8. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bouthiette as applied to claim 1 above, and further in view of Croce (4,762,230; hereinafter Croce).

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(A) As per Claim 4, Bouthiette fails to expressly disclose the method as recited in Claim 1, further comprising:

including a food item in at least one compartment wherein the food item is to be taken with the dosage group contained in the at least one compartment.

Nevertheless, this feature is old and well known in the art, as evidenced by Croce. In particular, Croce discloses the method as recited in Claim 1, further comprising:

including a food item in at least one compartment wherein the food item is to be taken with the dosage group contained in the at least one compartment (Croce: col. 6, lines 32-34).

One of ordinary skill would have found it obvious at the time of the invention to include the aforementioned feature of Croce within the Bouthiette system with the motivation of forming a sealed pocket for an article to be packaged (Croce: col. 6, lines 32-33).

(B) Claims 11 and 18 substantially repeat the same limitations as Claims 4 above, and are therefore rejected for the same reasons given for that claim.

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9. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bouthiette as applied to claim 1 above, and further in view of Kobylevsky et al. (6,493,427; hereinafter Kobylevsky).

(A) As per Claim 5, Bouthiette fails to expressly disclose the method as recited in Claim1, further comprising:

transmitting an order for medication to a pharmacy via a network.

Nevertheless, this feature is old and well known in the art, as evidenced by Kobylevsky. In particular, Kobylevsky discloses the method as recited in Claim1, further comprising:

transmitting an order for medication to a pharmacy via a network (Kobylevsky: col. 3, lines 20-42).

One of ordinary skill would have found it obvious at the time of the invention to include the aforementioned feature of Kobylevsky within the Bouthiette system with the motivation of providing a means for filling a prescription in a variety of ways (Kobylevsky: col. 6, lines 32-33).

(B) Claims 12 and 19 substantially repeat the same limitations as Claims 5 above, and are therefore rejected for the same reasons given for that claim.

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- 10. Claim 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bouthiette as applied to claim 1 above, and further in view of Sadler, Jr. et al. (4,830,407; hereinafter Sadler).
- (A) As per Claim 6, Bouthiette fails to expressly disclose the method as recited in Claim1, further comprising:

producing revised instructions to affix to the packaging.

Nevertheless, this feature is old and well known in the art, as evidenced by Sadler. In particular, Sadler discloses the method as recited in Claim1, further comprising:

producing revised instructions to affix to the packaging (Sadler: col. 4, lines 13-18).

One of ordinary skill would have found it obvious at the time of the invention to include the aforementioned feature of Sadler within the Bouthiette system with the motivation of providing a reminder system which may be desirably and optionally modified to meet the specific needs of a particular user (Sadler: col. 1, lines 65-67).

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Examiner notes also that under the Bouthiette system, a user may reprint a modified sealing sheet to reflect revised instructions and affix the revised sealing sheet to the packaging.

(B) As per Claim 7, Bouthiette fails to expressly disclose the method as recited in Claim 6, wherein the revised instructions comprise a revised dosage schedule.

Nevertheless, this feature is old and well known in the art, as evidenced by Sadler. In particular, Sadler discloses the method as recited in Claim 6, wherein the revised instructions comprise a revised dosage schedule (Sadler: col. 4, lines 13-15).

One of ordinary skill would have found it obvious at the time of the invention to include the aforementioned feature of Sadler within the Bouthiette system with the motivation of providing a reminder system which may be desirably and optionally modified to meet the specific needs of a particular user (Sadler: col. 1, lines 65-67).

Examiner also notes that under the Bouthiette system, a user may reprint a modified sealing sheet that comprises a revised dosage schedule.

(B) Claims 6, 7, 20 and 21 substantially repeat the same limitations as Claims 6 and 7 above, and are therefore rejected for the same reasons given for those claims.

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Conclusion

11. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. The cited but not applied art teaches a system for dispensing drugs in health care institutions (4,847,764); a pharmaceutical dosage distribution apparatus (4,019,793); a blister package and packaged tablet (6,155,423); components for making a strip package (3,630,346); a composite-packaging and control system (3,621,992); a medicament packaging device (3,503,493); a package and method for dispensing of pharmaceutical preparations (3,497,982); a drug delivery management system (US2002/0017996); a vitamin organizing, storing and dispensing system (6,041,932); sealed containers with tabs and method of making the same (5,975,304); a strip pack (6,375,956); a medication collection system (6,625,952); a method of providing a therapeutic regimen and prefabricated container therefor (6,681,935); and a medicament dispense sensing device (6,244,462).

The cited but not applied prior art also includes non-patent literature articles by PR Newswire ("eMD.com's Consumer Healthcare Website to Expand Content Beyond Initial Chronic Disease Information" Dec. 17, 1999. PR Newswire. pg. 1.) and PR Newswire ("PlanetRx.com Offers Online Pharmacy Services to HIP" Apr. 17, 2000. PR Newswire. pg. 1.).

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mike Tomaszewski whose telephone number is (571)272-8117. The examiner can normally be reached on M-F 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571)272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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